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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,707	04/10/2001	James U. Morrison	26017-3	1778

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EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/829,707	MORRISON, JAMES U.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al (US Patent No. 6,309,663).

Applicants claim a method for producing an extended-release composition comprising mixing acarbose with a sustained release matrix to create said composition.

The Patel et al patent discloses preparation of pharmaceutical compositions that comprises mixing surfactants with a hydrophilic therapeutic agent (see abstract), whereby the hydrophilic therapeutic agent may be selected as acarbose (see column 31, lines 57 and 58). Patel et al discloses that the pharmaceutical compositions may be in dosage forms, whereby the dosage form may be formulated as a tablet (see column 38, lines 1-3) as mentioned in instant Claim 2. The Patel patent discloses that the dosage form can be designed for extended release, which can be effected by a coated matrix composition. See the 3rd paragraph of column 38 and the first paragraph of column 40 for examples of cellulose derivatives that can be used to form the coating composition that include ethyl cellulose, hydroxpropyl cellulose, methyl cellulose, hydroxyethyl cellulose, hydroxymethyl cellulose, hydroxypropyl methyl cellulose phthalate, and hydroxypropyl methyl cellulose succinate. These cellulose derivatives

encompass the subject matter of instant Claims 11 and 14. The Patel et al patent further discloses the present of other additives in the pharmaceutical compositions that include fillers and lubricants (see column 36, 4th paragraph) as set forth in instant Claims 5 and 7. The Patel et al patent discloses that pharmaceutically acceptable bases such as magnesium aluminum silicate and synthetic aluminum silicate (see column 37, lines 2 and 3) may be added to the composition, which fall within the broadly recited colloidal silica that is set forth in instant Claims 6 and 8. See Table 18 in column 23 of the Patel et al patent whereby sodium lauryl sulfate and sodium stearyl fumarate may be included in the pharmaceutical composition of the Patel et al patent, which are also set forth in instant Claim 9. The Patel et al patent further discloses magnesium stearate as part of the pharmaceutical composition, which is disclosed in instant Claim 10. In column 54, line 26, Patel et al discloses that the amount of acarbose present in the composition thereof ranges from 50 to 100 mg, which is within the range of the amount of acarbose set forth in instant Claim 4 and also fall within the 20% to about 40% range of the tablet set forth in instant Claim 3. The above describe preparation of the pharmaceutical composition of the Patel et al patent that comprises mixing acarbose and a coating anticipates the instantly claimed method for producing an extended-release composition comprising mixing acarbose with a sustained release matrix to create a composition.

3. Claims 15-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al (US Patent No. 6,309,663).

Applicants claim a chemical composition comprising acarbose and a sustained release matrix.

The Patel et al patent discloses a pharmaceutical composition that comprises surfactants and a hydrophilic therapeutic agent (see abstract), whereby the hydrophilic therapeutic agent may be selected as acarbose (see column 31, lines 57 and 58). Patel et al discloses that the pharmaceutical compositions may be in dosage forms, whereby the dosage form can be designed for extended release, which can be effected by a coated matrix composition (see column 38, 2nd paragraph). See the 3rd paragraph of

column 38 and the first paragraph of column 40 for examples of cellulose derivatives that can be used to form the coating composition that include ethyl cellulose, hydroxpropyl cellulose, methyl cellulose, hydroxyethyl cellulose, hydroxymethyl cellulose, hydroxypropyl methyl cellulose phthalate, and hydroxypropyl methyl cellulose succinate. These cellulose derivatives encompass the subject matter of instant Claims 24-27. The Patel et al patent further discloses the present of other additives in the pharmaceutical compositions that include fillers and lubricants (see column 36, 4th paragraph) as set forth in instant Claims 18 and 20. The Patel et al patent discloses that pharmaceutically acceptable bases such as magnesium aluminum silicate and synthetic aluminum silicate (see column 37, lines 2 and 3) may be added to the composition, which fall within the broadly recited colloidal silica that is set forth in instant Claims 19 and 21. See Table 18 in column 23 of the Patel et al patent whereby sodium lauryl sulfate and sodium stearyl fumarate may be included in the pharmaceutical composition of the Patel et al patent, which are also set forth in instant Claim 22. The Patel et al patent further discloses magnesium stearate as part of the pharmaceutical composition, which is disclosed in instant Claim 23. In column 54, line 26, Patel et al discloses that the amount of acarbose present in the composition thereof ranges from 50 to 100 mg, which is within the range of the amount of acarbose set forth in instant Claim 17 and also fall within the 20% to about 40% range of the composition set forth in instant Claim 16. The above describe pharmaceutical composition of the Patel et al patent comprising acarbose and a coating anticipates the instantly claimed chemical composition comprising acarbose and a sustained release matrix.

4. Claims 28-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Bremer et al (US Patent No. 5,643,874).

Applicants claim a method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient.

The Bremer et al patent discloses glucosidase and/or amylase inhibitors that can be manufacture as pharmaceutical compositions for the combined use with a lipase inhibitor in the treatment of obesity (see column 1, line 27 and column 2, lines 1-3). The

Bremer et al patent discloses that the glucosidase and/or amylase inhibitor may be selected as acarbose (see column 2, lines 5-12). The Bremer et al patent discloses that the acarbose may be present in tablets that have controlled active substance release and increase residence time in the stomach (see Example D in column 6) which is within the meaning of the phrases "delayed release matrix" and "sustained release matrix" that is set forth in instant Claims 29 and 30. Example D discloses that the tablet comprises 50 mg of acarbose, which covers the amount of acarbose set forth in instant Claims 31 and 32. Example D sets forth the tablet as further comprising hydroxypropylmethycellulose, which is analogous to the hydroxypropylmethylcellulose that is disclosed in instant Claim 39; magnesium stearate, which is analogous to the magnesium stearate set forth in instant Claims 35 and 38; colloidal silicic acid, which is analogous to the colloidal silica set forth in instant Claim 36; and hydroxypropylmethylcellulose that is part of the coating film, which is analogous to the subject matter of instant Claims 40 and 41. See column 5, 6th paragraph, whereby the Bremer et al patent discloses the compositions thereof as being useful for oral application with the usual pharmaceutical adjuvant material, for example, organic or inorganic inert carrier materials, such as water, gelatin, lactose, starch, talc, gums, polyalkyleneglycols and the like, and Bremer et al discloses that the pharmaceutical adjuvant materials include preservatives, stabilizers, wetting or emulsifying agents, salts to change the osmotic pressure or to act as buffers, which are analogous to the broadly claimed filler, glidant, and lubricant that are set forth in instant Claims 33-35. The above describe method for treating obesity of the Bremer et al patent anticipates the instantly claimed method of treating a patient to stimulate weight loss.

5. Claims 15-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bremer et al (US Patent No. 5,643,874).

The composition used to treat obesity in the Bremer et al patent as describe in the above rejection also covers the composition set forth in Claims 15-27 of the instant application. Accordingly, Claims 15-27 also are rejected under 35 U.S.C. 102 as being anticipated by the Bremer et al patent.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 28-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bremer et al (US Patent No. 5,643,874) in view of Patel et al (US Patent No. 6,309,663).

Applicants claim a method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient.

The Bremer et al patent discloses glucosidase and/or amylase inhibitors that can be manufacture as pharmaceutical compositions for the combined use with a lipase

inhibitor in the treatment of obesity (see column 1, line 27 and column 2, lines 1-3), whereby the glucosidase and/or amylase inhibitor may be selected as acarbose (see column 2, lines 5-12). The information disclosed in the Bremer et al patent with regard to the treatment of obesity is substantially similar to the instantly claimed method of treating a patient to stimulate weight loss except for the limitation in instant Claim 42 whereby the coating used in the instant claimed method is a cellulose ether-based coating in combination with ethyl cellulose. The Patel et al patent shows that coatings that are cellulose ether–base coating in combination with ethyl cellulose is known in the art. See the first paragraph of column 40, which discloses coatings that may comprise cellulose derivatives including ethyl cellulose. See line 31 of column 40 whereby the Patel patent discloses combinations of the above materials can also be used which include ethyl cellulose and cellulose ether derivatives. The coatings disclosed in the Patel patent may be used to coat acarbose containing compositions. See column 31, lines 57 and 58 of the Patel patent whereby acarbose is a preferred hydrophilic therapeutic agent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute coating used to coat the pharmaceutical composition used to treat obesity of the Bremer et al patent with a coating of cellulose ether-based in combination with ethyl cellulose in view of the recognition in the art, as evidenced by the Patel patent at lines 26-31 of column 39, that coatings of cellulose derivatives that may comprise ethyl cellulose allows for balancing enhancement effectiveness, active protection, and safety liability through coating controlled dilution of the hydrophilic therapeutic agent, upon administration through delayed release or sustained release.

Summary

8. All the pending claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

9. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reach on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E.White

JAMES O. WILSON
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